K111512

510(k) Summary

OCT 2 6 2011

Submitted By

Thompson MIS
45 Stiles Rd, Suite 210
Salem, NH 03079

Contact: Frank Sullivan
Telephone: 603-912-5306
Date Prepared: October 4, 2011

Device Name and Classification:

Common Name: Intervertebral Fusion Device with Bone Graft, Lumbar

Proprietary Name: BoneBac™ T-PLIF Intervertebral Body Fusion Device System

Classification Name: Intervertebral Fusion Device with Bone Graft, Lumbar

Regulation and Classification: 21 CFR 888.3080, Class II

Product Code: MAX

Predicate Devices

K100042 – DiFusion Technologies XIPHOS IBF System
K071724 – Spinal Elements Lucent
K072791 – Synthes Opal
K071795 – Nuvasive Coroent
K080537 – Kiscomedica L-Varlock

Device Description

The BoneBac™ T-PLIF Intervertebral Body Fusion Device is a spinal intervertebral body fusion device system comprised of implants with a variety of lengths, widths, and heights to accommodate patient anatomy. The implants are made of Solvay Zeniva ZA-500 PEEK (ASTM F2026). The devices have raised contours on the superior and inferior surfaces that will resist device movement following implant. The devices contain radiographic markers to enable fluoroscopic visualization.

Intended Use

The BoneBac™ T-PLIF Intervertebral Body Fusion Device System is indicated for use in skeletally mature patients who have had six months of non-operative treatment. The device is intended for the treatment of degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolithesis at the involved level(s).

The BoneBac™ T-PLIF Intervertebral Body Fusion Device System is intended to be used with supplemental spinal fixation system(s) cleared for use in the lumbar spine and autogenous bone graft to facilitate fusion.

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history or radiographic studies.

Technological Characteristics

The BoneBac™ T-PLIF Intervertebral Body Fusion Device System was shown to share the same technological characteristics with predicate devices through comparison of indications for use, function, operating principles, and materials.

Basis for Substantial Equivalence

The BoneBac™ T-PLIF Intervertebral Body Fusion Device System was evaluated in accordance with FDA Document, *Class II Special Controls, Guidance Document: Intervertebral Fusion Device, June 12, 2007*, and has been found to meet criteria defined in the guidance document. The system shares the same intended use, technological characteristics, operating principles, and materials with predicate devices. Mechanical testing demonstrates substantially equivalent performance. Clinical data was not required for this device. Mechanical test comparisons were conducted per the following standard test methods:

- ASTM F2077-03, Static and Dynamic Axial Compression, Static Torsion, and Static and Dynamic Shear Compression
- ASTM F2267-04, Subsidence Under Static Axial Compression
- ASTM Draft Standard F-04.25.02.02, Static Expulsion
- ASTM F1877 Wear Debris Characterization

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 26 2011

Thompson MIS, Inc.
% Mr. Frank Sullivan
45 Stiles Road, Suite 210
Salem, New Hampshire 03079

Re: K111512
Trade/Device Name: BoneBac™ T-PLIF Intervertebral Body Fusion Device System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 04, 2011
Received: October 05, 2011

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if Known): K111512

Indications For Use:

The BoneBac™ T-PLIF Intervertebral Body Fusion Device System is indicated for use in skeletally mature patients who have had six months of non-operative treatment. The device is intended for the treatment of degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolithesis at the involved level(s).

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Prescription Use: X **AND/OR** **Over-The-Counter Use:** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111512